Application No.: 10/764,786
Attorney Docket No.: SAR 15036 (18703-538)

REMARKS

Upon entry of this response, claims 1-18 will be pending in the present application.

I. Claims 1-18 Are Not Obvious

Claims 1-18 have been rejected under 35 U.S.C. § 103(a) as allegedly being *prima facie* obvious over U.S. Patent No. 6,695,982 ("the Chen reference") in view of U.S. Patent No. 4,898,733 ("the DePrince reference") in view of U.S. Published Patent Application No. 2002/0102307 A1 ("the Guo reference") and in further view of U.S. Patent No. 6,340,360 B1 ("the Lyles reference") (cumulatively, "the cited references"). Applicants traverse the rejection and respectfully request reconsideration thereof.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or incentive in the reference(s), coupled with the knowledge generally available to one of ordinary skill in the art at the time of the invention, that motivate modifying the reference or to combine the teachings of the references. Second, there must be a reasonable expectation of success in modifying the reference or combining the teachings of the references. Finally, the reference (or references when combined) must teach or suggest all the claimed limitations of the claimed invention.

Further, both the teaching or suggestion to make the claimed invention and the reasonable expectation of success must be found in the references and not be based on the Applicants' disclosure. *In re Vaeck*, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Regarding the motivation requirement, the motivation to modify the prior art (*i.e.*, cited references) must flow from some teaching in the prior art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. *Alza Corp. v. Mylan Labs Inc. 391 F.3d 1365, 1372-73 (Fed. Cir. 2004)*. Noteworthy is this regard are the following quotations:

> [t]he mere fact that the prior art could be so modified would not have made the modification obvious unless the

> prior art suggested the desirability of the modification. *In re Laskowski,* 871 F.2d 115, 117 (Fed. Cir. 1989) (quoting *In re Gordon,* 733 F.2d 900, 902 (Fed. Cir. 1984); and
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> [a]ccordingly, an examiner cannot establish obviousness by locating references which describe various aspects of a patent applicant's invention without also providing *evidence* of the motivating force that would *impel* one skilled in the art *to do what the patent applicant has done. Ex parte Levengood,* 28 U.S.P.Q.2d 1300, 1302 (Pat. Off. Bd. App. 1993) (emphasis added).

Significantly, the U.S. Patent & Trademark Office ("the Office") provides no *evidence* of the motivating force that would *impel* one skilled in the art to modify the respective teaching of the cited references *"to do what the patent applicant has done,"* and arrive at the claimed invention. Rather, the Office's assertion that it would have been obvious for "a skilled artisan to combine the teaching of Chen, DePrince, Guo and Lyles in order to make the device as claimed" where "[t]he motivation to combine the [cited references] would be a drug delivery device [of the claimed invention]" (*see* Office Action date May 17, 2006 ("the Office Action"), p. 5) is, respectfully, an "[un]convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the [cited] references" (*Ex parte Clapp,* 227 U.S.P.Q. 972, 973 (Bd. Pat. App. & Int. 1985), especially, when the cited references do not expressly or impliedly teach or suggest the claimed elements or claimed combination of the claimed invention.

For example, in alleging that the claimed invention is obvious in view of the cited references, the Office asserts that the Chen reference discloses a controlled-release drug delivery system comprising an inflexible sleeve with a first controlled-release layer (10) and a second controlled-release layer (15), which are deposited within the sleeve and are spaced apart from one another, thereby defining a drug-retaining region (5) between the controlled-release layers, and which permit a delayed drug release into an ambient

environment when in contact with body fluid. *See* the Office Action, pp. 2-3. However, though the Chen reference discloses a sustained release drug delivery device having a first and a second layer (amongst a third; *see, e.g.,* the Abstract), these two layers are not equivalent to the first and second layers of the claimed invention.

For example, claim 1 of the claimed invention comprises a first controlled-release layer (106) and a second controlled-release layer (106) that are disposed *within* a sleeve (102) (not present in the Chen reference) such that they are "spaced-apart from one another, defining a drug-retaining region in the space between said controlled-release layers." Thus, the first and second controlled-release layers of the claimed invention have a shape that approximates the cross section of the sleeve such that when each is disposed *inside* the sleeve each creates a wall at one open end of the sleeve so as to be *only one side* of the drug-defining region. (*See also, e.g.,* FIG. 2 and paragraph [0058] of the specification of the claimed invention).

By contrast, the Chen reference teaches a first coating layer (10) and a second coating layer (15) that surround the drug-defining region, (*"inner core or reservoir"*) so as to *coat* this region. *See, e.*g., Abstract and FIG. 1. The, first and second *coating* layers of the Chen reference are different from the first and second controlled-release layers of the claimed invention because the *coating* layers of the Chen reference *coat* the drug-defining region, whereas the controlled-release layers of the claimed invention do *not coat* the drug-defining region, but rather, reside in the sleeve, *e.g.,* perpendicular to the body of the sleeve, so as to create a side of the sleeve. The Chen reference, therefore, does not teach the first and second controlled-release layers of the claimed invention.

Moreover, the Chen reference fails to suggest the desirability or incentive to make the modification needed of its first and second *coating* layers to arrive at the first and second controlled-release layers of the claimed invention. Further, the Office evidences no motivating force that would impel one skilled in the art to modify the Chen reference to achieve the first and second controlled-released layers of the claimed invention, much less to achieve the controlled-released drug delivery systems of the claimed invention.

Further, the Office asserts that the discs (18, 19) of the Chen reference teach the sealing surfaces (104) of the claimed invention. *See, e.g.,* the Office Action, p. 3. The Office is respectfully mistaken.

For example, the sealing surfaces (104) of claim 5 of the claimed invention are areas *of* the sleeve (100), such as ledges in the interior of the sleeve, which enable a seal to form when a controlled-release layer (106) is disposed inside the sleeve (100) by placement between a sealing surface (104) *of* the sleeve (100) and a cap (112) of the claimed invention. *See, e.g.,* paragraph [0057] and FIG. 2 of the specification of the claimed invention.

By contrast, the discs (18, 19) of the Chen reference are *discrete* physical elements of the second coating layer. *See, e.g.,* FIG. 1. Also, discs (18, 19) are impermeable to drug transfer from the drug-defining region to outside the region. Thus, the Chen reference's discs are different to the claimed invention's sealing surfaces because they are *discrete* elements of the device of the Chen reference *that* prevent the leakage of the effective agent from the drug-defining region (*see, e.g.,* column 5, lines 25-27), while the sealing surfaces of the claimed invention (104) are *not discrete* elements, but are physically *part of* the sleeve, and *in combination with* the controlled-release layer (106) and cap (112), they provide a seal between the drug-defining region and outside environment, thereby preventing the leakage of an effective agent from the drug-defining region. The Chen reference, therefore, does not teach the sealing surfaces of the claimed invention.

Moreover, the Chen reference fails to suggest the desirability or incentive to make the modification needed of its discs to arrive at the sealing surfaces of the claimed invention. Further, the Office evidences no motivating force that would impel one skilled in the art to modify the Chen reference to achieve the sealing surfaces of the claimed invention, much less to achieve the controlled-released drug delivery systems of the claimed invention.

Additionally, the Office's assertions that other disclosures of the Chen reference make the claimed invention obvious (*e.g.,* disclosures that its "controlled-release layers

control the rate of diffusion of body fluid into and out of the drug-defining region" and that its drug delivery device can comprise cellulose acetate butyrate (*see, e.g.*, the Office Action, p. 3) are moot. Because the Chen reference fails to teach the controlled-release layers and sealing surfaces of the claimed invention, much less the controlled-release drug delivery device of the claimed invention (which the Office acknowledges; *see, e.g.*, the Office Action, pp. 3-4) (as described above), disclosure of these other claimed characteristics, which are narrower embodiments of the claimed invention (*see, e.g.*, dependent claims 3 and 15, respectively, and independent claim 1), is moot.

Furthermore, the DePrince reference cannot correct the deficiencies of the Chen reference. Although the DePrince reference "discloses a layered compression molded device for the sustained release of a beneficial agent with a sleeve that is open at both ends," as the Office asserts (*see, e.g.*, the Office Action, p. 4), this disclosure fails to teach or suggest the sleeve of the claimed invention. For example, claim 1 of the claimed invention claims an "inflexible sleeve" open at both ends having two controlled-release layers "disposed within said sleeve" such that the controlled-release layers "are space-apart from one another, defining a drug-retaining region in the space between said controlled-release layers.

Yet the DePrince reference merely discloses that its tablet delivery system may be placed in a sleeve having one or both ends open. *See* col. 5, lines 56-68 to col. 6, lines 1-13. The sleeve of the DePrince reference is different than the sleeve of the claimed invention because the DePrince reference fails to teach an inflexible sleeve open at both ends having two controlled-release layers "disposed within said sleeve" to provide a drug-retaining region in said sleeve in the space between said controlled-release layers.

Further, the DePrince reference fails to suggest the desirability or incentive to make the modification needed of its sleeve, such as, being inflexible and/or comprising two controlled-release layers in the manner of the claimed invention, to arrive at the sleeve of the claimed invention. In fact, the DePrince reference is silent with respect to modifications of its sleeve to arrive at the sleeve of the claimed invention, not to mention to arrive at the controlled-release drug delivery system of the claimed invention.

The Office also evidences no motivating force that would impel one skilled in the art to modify the drug delivery device of the Chen reference in light of the DePrince reference to arrive at the controlled-release drug delivery system of the claimed invention. Thus, because the Chen reference fails to teach or suggest the elements of the claimed invention asserted by the Office as being taught by it (*e.g.*, the sealing surfaces), much less the controlled-release drug delivery system of the claimed invention (as discussed above), and because the DePrince reference fails to teach or suggest the elements of the claimed invention asserted by the Office as being taught by it (*e.g.*, a sleeve having sealing surfaces), much less the controlled-release drug delivery system of the claimed invention, the claimed invention is unobvious over the Chen reference in view of the DePrince reference.

Likewise, the Guo reference cannot correct the deficiencies of the Chen reference and the DePrince reference and thus, does not make the claimed invention obvious. The Office asserts that the Guo reference "discloses a sustained delivery device with a first cap having an open center and being received by the first end of a sleeve and abuts a marginal region of a controlled release layer and a second cap which has an open center and being received by the [second] end of a sleeve and abuts a marginal region of a controlled release layer." *See, e.g.*, the Office Action, p. 4. The Office respectfully is mistaken.

For example, *both* caps of the claimed invention abut a controlled-release layer of the claimed invention and have an opening that is centrally located in the cap so as to give the caps a "ring" configuration. *See, e.g.*, Claim 6 and paragraphs [0009] and [0059]). The central opening of the cap allows *the controlled-release layer*, which is sandwiched between the cap and a sealing surface of the sleeve (*see, e.g.*, paragraph [0011]), exposure to bodily fluids to *affect release of the agent* from the drug-defining region.

By contrast, although the drug delivery device of the Guo reference has a first cap (or "plug") (116, 216), which may abut a marginal region of "a controlled-release layer," in the form of a permeable outer layer (210) (*see, e.g.*, paragraph [0062]), and may have a

second cap (242, 316), this second cap does not abut a marginal region of "a controlled-release layer." Rather, this second cap abuts the impermeable inner tube (212, 312). *See, e.g.*, FIGS. 2-3; paragraphs [0058] and [0067]. Moreover, the caps of the Guo reference (116, 242, 316) are "essentially impermeable to the passage of the effective agent," (*see, e.g.*, paragraph [0081]), while *cap (216) is often permeable* to the agent and thus, *provides the only diffusion pathway for the agent* out of the drug-defining region (*i.e.*, "reservoir"). *See, e.g.*, paragraphs [0058] and [0063]. Further, the Guo reference merely states that when the cap (216) is impermeable to the agent, the caps (242), (216) can have "a hole or holes...drill[ed]" through them to affect release of the agent from the reservoir (*see, e.g.*, paragraph [0062]).

Thus, the caps of the Guo reference are different than the caps of the claimed invention because, e.g., they are not "ring-configured" with an opening centrally located therein and they are often impermeable or directly control the rate of diffusion of an effective agent from the drug-defining region, while the caps of the claimed invention are "ring-like" with a centrally-located opening that allows the controlled-release layer, which is behind the cap, to control diffusion of an effective agent from the drug-retaining region. Thus, Guo reference does not teach the placement or extent of a hole(s) to arrive at the ring-configured caps of the claimed invention. Nor does the Guo reference teach diffusion of the effective agent from a controlled-release layer internal to (i.e., behind) the cap.

Additionally, the Guo reference fails to teach or suggest the desirability or incentive to make the modifications needed of its caps to arrive at the ring-configured caps of the claimed invention. In fact, the Guo reference is silent with respect to modifications of its caps to achieve caps that "are ring-like, with open central regions" like those of the claimed invention, much less the controlled-release drug delivery system of the claimed invention.

Further, the Office evidences no motivating force that would impel one skilled in the art to modify the drug delivery device of the Chen reference in view of the DePrince reference in view of the Guo reference to arrive at the controlled-release drug delivery

system of the claimed invention. Moreover, because the Chen reference fails to teach or suggest, the elements of the claimed invention asserted by the Office as being taught by it (*e.g.*, the sealing surfaces), much less the controlled-release drug delivery system of the claimed invention (as discussed above), and because the DePrince reference fails to teach or suggest the elements of the claimed invention asserted by the Office as being taught by it (*e.g.*, a sleeve having sealing surfaces), much less the controlled-release drug delivery system of the claimed invention (as discussed above), and because the Guo reference fails to teach or suggest the elements of the claimed invention asserted by the Office as being taught by it (*e.g.*, ring-like caps) much less the controlled-release drug delivery system of the claimed invention, the claimed invention is unobvious over the Chen reference in view of the DePrince reference in view of the Guo reference.

The Lyles reference, however, cannot correct the deficiencies of the Chen reference, the DePrince reference and the Guo reference, and thus, does not make the claimed invention obvious. The Office asserts that the Lyles reference "teaches a dose unit in which the drug is disposed adjacent to first and second end[s] of a sleeve outside of a drug retaining region." *See, e.g.*, the Office Action, p. 5. The Office respectfully is mistaken, and thus, the Lyles reference does not teach the position of a dose unit of the claimed invention, nor the controlled-release drug delivery system of the claimed invention.

For example, a dose unit can be positioned in at least three areas of a controlled-release drug delivery system of the claimed invention. First, as claimed in, *e.g.*, claim 1, a dose unit can be position within the drug-retaining region ("liquid-tight region"), which is the region between the first and second controlled-release layers. *See also, e.g.*, paragraph [0012]. Second, as claimed in, *e.g.*, claim 8, a dose unit can be "disposed adjacent said first end of said sleeve *outside of the drug-defining region* (*e.g.*, on the other side of the first controlled-release layer forming that end of the drug-defining region). *See, e.g.*, paragraph [0012]. Third, as claimed in, *e.g.*, claim 8, a dose unit can be "disposed adjacent said second end of said sleeve *outside of the drug-defining region* (*e.g.*, on the other side of the second controlled-release layer forming that end of the

drug-defining region). *See, e.g.*, paragraph [0012]. Further, more than one dose unit can be disposed at each of these areas. *See, e.g.*, paragraph [0012].

On the other hand, the Lyles reference teaches that one or more drugs can be positioned *in a drug-defining region* (i.e., "reservoir). *See, e.g.*, col. 13, lines 35-55. To achieve differing rates of drug delivery, the drug-defining region may have segments *within which a drug is contained*, or multiple drug-defining regions *containing* different drugs may be used ("inserted") simultaneously. *Id.* The Lyles reference, however, does not teach disposing a drug *outside of the drug-defining region*.

Additionally, the Lyles reference fails to suggest the desirability or incentive to make the modifications needed in order to dispose a drug *outside the drug-defining region* of its drug delivery system so as to arrive at the *outside the drug-defining region* position of a drug dose of the claimed invention. In fact, the Lyles reference is silent with respect to modifications of its drug dose positions to achieve the drug dose positions (i.e., inside *and outside* the drug-defining region) of the claimed invention, much less to achieve the controlled-release drug delivery system of the claimed invention.

The Office also evidences no motivating force that would impel one skilled in the art to modify the drug delivery device of the Chen reference in view of the DePrince reference in view of the Guo reference in further view of the Lyles reference to arrive at the controlled-release drug delivery system of the claimed invention. Moreover, because the Chen reference, the DePrince reference and the Guo reference each fail to teach or suggest the respective element(s) of the claimed invention asserted as taught by the Office, much less the controlled-release drug delivery system of the claimed invention (as discussed above), the claimed invention is unobvious over the Chen reference in view of the DePrince reference in view of the Guo reference and in further view of the Lyles reference.

Respectfully, the Office's reasoning that one skilled in the art would find the controlled-release drug delivery system of the claimed invention obvious in view of the teachings of the cited references is at most an assertion that one skilled in the art could have found the claimed drug delivery system "obvious to try" in view of the cited

references. "But whether a particular combination might be 'obvious to try' is not a legitimate test of patentability." *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988). As discussed above, the cited references are not sufficient, either alone or in combination, to teach or suggest - and thus, motivate - one of ordinary skill in the art "to do what the applicant has done."

Moreover, the mere possibility that the cited references can be modified does not itself provide the requisite motivation for obviousness. *In re Dien*, 152 U.S.P.Q. 550 (C.C.P.A. 1967) (holding that the incentive to seek improvement in existing process did not render change made by applicant obvious, even where change was one capable of being made from a theoretical point of view). The mere possibility for modification and improvement is not the "motivating force" that the Patent Office Board of Appeals and the Federal Circuit have invariably required. If it were, then all inventions would be obvious since some change always is possible. On the contrary, an invention is obvious under patent law only when the claimed means for effecting an improvement - as opposed to the possibility of trying any and all means - is suggested by the prior art. Significantly, as discussed previously, none of the cited references would have motivated one skilled in the art to make the substantial modifications that would be necessary to produce the claimed invention. It is only with improper use of hindsight and the benefit of Applicants' disclosure that one can discern the desirability of the controlled-release drug delivery system now claimed in the present invention. The following quote from *Grain Processing Corp. v. Am. Maize-Prods. Co.*, 5 U.S.P.Q.2d 1788, 1792 (Fed. Cir. 1988) is particularly noteworthy in this regard:

> "Using an applicant's disclosure as a blueprint to reconstruct the claimed invention from isolated pieces of the prior art contravenes the statutory mandate of § 103 which requires judging obviousness at the point in time when the invention was made."

Consequently, the Office has failed to establish at least the first criteria (as stated above) required to establish a *prima facie* case of obviousness. No motivation to

combine the cited references has been set forth that does not improperly use Applicants' disclosure and hindsight. At most, the Office asserts that it is "obvious to try" combining the cited references to arrive at the claimed invention. Again, an improper basis for finding obviousness. Therefore, because the Office has failed to point to motivation sufficient for combining the cited references, *prima facie* obviousness has not been established. Accordingly, Applicants' respectfully request reconsideration and withdrawal of the § 103 rejection of the claims of the claimed invention.

II. Conclusion

Applicants believe the claims are in a condition for allowance, and therefore, earnestly solicit an early Notice of Allowance. The Office is invited to contact Applicants' undersigned attorneys at (973) 597-2500. All correspondence should be directed to our address listed below.

Respectfully submitted,
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